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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,551

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Jeak Ling Ding

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EXAMINER

DUFFY, PATRICIA ANN

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,551	Applicant(s) DING ET AL.	
	Examiner Patricia A. Duffy	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6-17-09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-16, 32-34, 36 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7, 15, 16, 32-34 and 38 is/are allowed.
- 6) ☒ Claim(s) 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

The amendment and response filed 6-17-09 has been entered into the record. Claims 8, 9, 17-31, 35 and 37 have been cancelled. Claims 1-7, 10-16, 32-34, 36 and 38 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

The rejection of claims 15, 16 and 22 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29 and 30 of U.S. Patent No. 6,719,973 issued April 13, 2004 is withdrawn in view of Applicants amendments to the claims.

The rejection of claims 1-8, 14 and 36-38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 12, 20 and 27-36 of U.S. Patent No. 6,719,973 in view of Tam et al (Eur. J. Biochem. 269:923-932, 2002) is withdrawn in view of the amendment to the claims.

The rejection of claims 1-12, 14-16, 32-34 and 36-38 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicant's amendment to the claims.

The rejection of claims 1-16, 32-34 and 36-38 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claims.

The rejection of claims 15 and 16 under 35 U.S.C. 102(b) as being clearly anticipated by Tan et al (The FASEB Journal, 14:1801-1813, September 2000) is withdrawn in view of the amendment to the claims.

The rejection of claims 1-5, 8, 10 and 11 under 35 U.S.C. 102(a) as being clearly anticipated by Li et al (Protein Engineering, 16(8):629-635, August 2003) is withdrawn in view of the amendment to the claims.

The rejection of claims of claims 15, 16 and 32-34 under 35 U.S.C. 102(e) as being anticipated by Ding et al (US Patent No. 6,719,973 issued April 13, 2004 with priority to July 26, 2000) is withdrawn in view of the amendment to the claims.

The rejection of claims 1-8, 14 and 36-38 under 35 U.S.C. 103(a) as being unpatentable over Ding et al (US Patent No. 6,719,973 issued April 13, 2004 with priority to July 26, 2000) in view of Tam et al (Eur. J. Biochem. 269:923-932, 2002) is withdrawn in view of the amendment to the claims.

The rejection of claims 1-8, 14 and 36-37 under 35 U.S.C. 103(a) as being unpatentable over Tan et al (The FASEB Journal, 14:1801-1813, September 2000) in view of Tam et al (Eur. J. Biochem. 269:923-932, 2002) is withdrawn in view of the amendment to the claims.

Rejections Maintained

Claim 12 stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 12, 20 and 27-36 of U.S. Patent No. 6,719,973 in view of Tam et al (Eur. J. Biochem. 269:923-932, 2002) for reasons made of record in the Office Action mailed 3-17-09.

Applicant's amendment does not obviate this rejection because claim 12 is found to be broadening and excludes the new limitation of having a protease cleavable linker sequence.

Claim 12 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al (US Patent No. 6,719,973 issued April 13, 2004 with priority to July 26, 2000) in view

of Tam et al (Eur. J. Biochem. 269:923-932, 2002) for reasons made of record in the Office Action mailed 3-17-09.

Applicant's amendment does not obviate this rejection because claim 12 is found to be broadening and excludes the new limitation of having a protease cleavable linker sequence.

Claim 12 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Tan et al (The FASEB Journal, 14:1801-1813, September 2000) in view of Tam et al (Eur. J. Biochem. 269:923-932, 2002) for reasons made of record in the Office Action mailed 3-17-09.

Applicant's amendment does not obviate this rejection because claim 12 is found to be broadening and excludes the new limitation of having a protease cleavable linker sequence.

New Rejections Based on Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 11 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are drawn to a polypeptide comprising more than one S3 peptides wherein at least two of the s3 peptides are separated by a linking sequence cleavable by a protease (claim 1) and dependent claims wherein at least one of the linking sequence is cleavable acid digestion. The specification contemplates linkers that are not cleavable in combination with a linker that is cleavable (see specification page 3, lines 19-25). The specification at page 4, last line, indicates that the cleavage method may be acid digestion *or* proteolytic digestion. The specification at page 5, lines 12-14 again describes cleavable linkers in the alternative. The specification does not describe or reduce to practice a polypeptide comprising more than one S3 peptide having two different cleavable linkers (i.e. proteolytic and acid digestion) as is now claimed. In each case, the specification describes the use of these cleavable linkers in the alternative. The original claims indicate that they were used separately. As such, the amendment of the claims to recite both types of linkers in the same polypeptide is deemed new matter. Should Applicants wish to dispute this issue, they should point to the specification by page and line number were conception by way of written description this newly claimed embodiment can be found.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is confusion because it is unclear what Applicants intend by the language "any one tagged". Since there is only one polypeptide the metes and bounds of this

limitation cannot be ascertained. Further, this claim appears to be a duplicate of amended claim 15. Clarification is respectfully requested.

Claim Objections

Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 1 requires the polypeptide to comprise S3 peptides and a protease cleavable linker sequence. However the polypeptide of claim 12 indicates that the polypeptide consists only of S3 peptides. As such, the claim is read to exclude the linker of claim 1 and as such is broadening.

Status of Claims

Claims 1-7, 15, 16, 32, 33, 34, 38 and 38 are allowable. Claims 10-14 stand rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisors, Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/
Primary Examiner